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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,564	10/10/2001	Alexander Fred Markham	5585-59367	4375
24197	7590	02/25/2004		
KLARQUIST SPARKMAN, LLP 121 SW SALMON STREET SUITE 1600 PORTLAND, OR 97204			EXAMINER TUNG, JOYCE	
			ART UNIT 1637	PAPER NUMBER

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/869,564

Applicant(s)

MARKHAM ET AL.

Examiner

Joyce Tung

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 7,10-16,18-35,37,41 and 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-9, 17, 36 and 38-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 08062001.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Following the entry of the second preliminary amendment filed 5/24/2003, the claims 1-42 are pending.

Election/Restrictions

1. Applicant's election with traverse of group I, claims 1-6, 36 and 38-40 in Paper No. 10292003 is acknowledged. The traversal is on the ground(s) that the response argues that in the corresponding International Preliminary Examination Report (IPER), claims 1-3, 8, 10-12, 14-17 and 20 were found to be novel and inventive over the prior art and these claims share special technical feature that establish unity of invention. As set forth in 37 C.F.R. §1.475, the unity of invention standard notes that unity is satisfied if there is a technical relationship among the invention involving the same special technical feature. However, these claims do not share the same special technical feature. Specifically, claims 10-12 are drawn to an antibody, which has the different chemical structure and function from the nucleic acid of claims 1-3 and claims 14-16 are drawn to the method of treatment by using nucleic acid or protein. Thus these claims do not share the same special technical features. Claim 20 depends from claim 19, which has non-elected sequence, SEQ ID NO: 3. Therefore, these claims should not be examined together. However, based upon the argument concerning Groups I, III, VI and VII examining together, claims 1-6, 8-9, 17, 36 and 38-40 are examined together.
2. Claims 7, 10-16, 18-35, 37 and 41-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected groups, there being no allowable generic or linking claims.

Claim Objections

3. Claims 2, 4, 8, 9, 17 are objected to because of the following informalities: the first letter of the phrase "claim" used in the claim language is not required to be capitalized. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 38-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention since there is no support in the specification that the nucleic acid of claim 1 comprises at least 75%, 85% or 95% identify to a nucleic acid sequence shown in SEQ ID NO: 39. In addition, claims 38-40 are not as originally filed. Therefore, it constitutes new matter.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 5-6 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how the expression of a nucleic acid sequence shown in SEQ

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ID NO: 1, or fragment or variants of the nucleic acid sequence shown in SEQ ID NO: 1 is detected for diagnosing orofacial clefting in a patient.

7. Claims 8-9 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 8-9 and 17 are confusing because the product claims 1-4 drawn to nucleic acid sequence are elected, while claims 8-9 and 17 involve nucleic acid or protein. It is suggested to amend the language to involve only the nucleic acid sequence.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 3-4, 17 and 36 are rejected under 35 U.S.C. 102(b) as anticipated by Derynck et al. (5,482,851, issued Jan. 1996)

Derynck et al. disclose nucleic acid sequence encoding TGF- β from human and porcine (See the Abstract and fig. 4a – 4c). The nucleic acid sequence of TGF- β is useful in diagnosis and identification of TGF- β (See the Abstract). The TGF- β has been used for wound healing (See column 1, lines 31-33 and column 14, lines 41-44). There is a nucleic acid sequence CCC at the position 18-20 of porcine nucleic acid sequence encoding TGF- β (See fig. 4a) which hybridizes to a nucleic acid sequence GGG at position 57-59 shown in SEQ ID NO: 1. The

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cDNA probe is hybridized under high stringency condition to RNA from tumor cell (See column 19 lines 61-62). The TGF- β cDNA probes are used for diagnosis in which the probes are in a buffer (See column 19, lines 61-62). Therefor, the teachings of Derynck et al. anticipate the limitations of the claims.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Derynck et al. (5,482,851, issued Jan. 1996)

The teachings of Derynck et al. are set forth in section 9 above. Derynck et al. do not disclose the high stringency condition for nucleic acid hybridization.

Derynck et al. disclose that the hybridization condition is at 42⁰C, 5X SSC and 0.1% SDS (See column 18, lines 50-67).

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One of the ordinary skill in the art at the time of the instant invention would have been motivated to optimize the condition with 1X SSC, 0.1% SDS at 65⁰C because optimizing the hybridization condition was routine practice in the art with a reasonable expectation of success. It would have been prima facie obvious to optimize the hybridization condition with 1X SSC, 0.1% SDS at 65⁰C.

12. Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Derynck et al. (5,482,851, issued Jan. 1996) as applied to claim 1, 3-6, 17 and 36 above, and further in view of Rolland et al. (6,184,037, issued Feb 6, 2001).

The teachings of Derynck et al. are set forth in section 9 above. Derynck et al. do not disclose a delivery vehicle comprising nucleic acid of claim 1 in a suspension form to deliver nucleic acid to a tissue.

Rolland et al. disclose a delivery vehicle in a suspension to deliver nucleic acid to a tissue (See column 7, lines 8-21).

One of ordinary skill in the art at the time of the instant invention would have been motivated to apply the deliver vehicle of Rolland et al. in a suspension to deliver the nucleic acid molecule to a tissue because the deliver vehicle of Rolland et al. increases the efficacy of transfection of a nucleic acid for internal administration (See column 7, lines 8-9 and column 4, lines 1-3). Thus, it would have been prima facie obvious to apply the deliver vehicle of Rolland et al. to deliver nucleic acid molecule of claim 1 in a suspension to a tissue.

Sequence Rules

13. In the sequence listing filed 8/06/2001, there is no SEQ ID NO: 39 listed and in the sequence listing filed 6/29/2001, there is SEQ ID NO: 39 listed. It is unclear which sequence listing is valid. Clarification is required.

Priority

14. As noticed that United Kingdom 9900167.9, issued 1/06/1999 does not have SEQ ID NO: 39, the priority date of the instant application is based upon the 371 of PCT of GB00/00003 filed 1/06/2000.

Summary

15. No claims are allowable.

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16. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

17. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung *JT*
February 11, 2004


ETHAN WHISENANT
PRIMARY EXAMINER